UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
CHATTANOOGA DIVISION

ALLAN J. TORTORICE AND LAURA L. TORTORICE, Plaintiffs, v. PFIZER, INC. Defendant.	**CASE NO.** **DEMAND FOR JURY TRIAL**

COMPLAINT

1. This is an action brought by Allen J. Tortorice (hereinafter "Plaintiff") and Laura L. Tortorice (hereinafter, "Derivative Plaintiff") against Pfizer, Inc. (hereinafter, "Defendant" or "Pfizer") to recover for his severe injuries arising from a left ventricular apical thrombus, blood clot, bilateral pleural effusions, pulmonary embolisms, and ascites which resulted in hospitalization, and multiple surgeries, all directly caused by his ingestion of Pfizer's heavily marketed prescription drug, Xeljanz.

2. This case involves warnings that were entirely absent from the Xeljanz product label and warnings that were severely understated therein. At the time of the thromboembolic event, there were no warnings for major adverse thromboembolic events (MACE) and thrombosis in Pfizer's Xeljanz label -available to prescribing physicians- or the United States Xeljanz Medication Guide, which Pfizer disseminates directly to patients, even though Pfizer was aware that Xeljanz caused these life-threatening reactions.

3. Pfizer intentionally failed to warn of dangerous and known risks associated with

Xeljanz, an oral Janus kinase (JAK) inhibitor approved for the treatment of adult patients with moderate to severely active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), and moderate to severely active ulcerative colitis (UC). Specifically, an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death. Pfizer concealed their knowledge of Xeljanz's unreasonably dangerous risks from Plaintiffs, other consumers, and the medical community.

4. After beginning treatment with Xeljanz, and as a direct and proximate result of Pfizer's actions and inaction, Plaintiff suffered serious injuries. Plaintiff's ingestion of Xeljanz caused and will continue to cause injury and damage to Plaintiffs.

5. Plaintiffs accordingly seek compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by Xeljanz.

JURISDICTION AND VENUE

6. This Court has diversity subject matter jurisdiction under 28 U.S.C. § 1332 because there is diversity of citizenship between the parties, and the amount in controversy exceeds $75,000. Specifically, Plaintiffs are citizens of the State of Tennessee and Plaintiff was prescribed the drug, purchased the drug, ingested the drug, was injured by the drug and was treated for resulting injuries in Tennessee, while Pfizer is a citizen of the State of Delaware and New York. Additionally, the drug was intentionally and purposefully marketed to and in Tennessee, including to medical professionals licensed in Tennessee by the State of Tennessee and the damages Plaintiff sustained as a result of Pfizer's intentional failure to warn of known, serious, and life-threatening side effects associated with Xeljanz substantially exceed $75,000.

7. Venue is appropriate in this Court under 28 U.S.C. § 1391(a) & (b) because a substantial part of the events and omissions giving rise to this action occurred in this district, and

because Plaintiffs reside and were injured in this district.

8. This Court has specific jurisdiction over Pfizer, because Pfizer produced, manufactured, marketed, sold, and failed to warn of the risks associated with the very Xeljanz pills that injured Plaintiff, all of which were prescribed to, sold to, and ingested by Plaintiff in Tennessee.

THE PARTIES

A. The Plaintiffs

9. At all relevant times, including at the time of his Xeljanz-related injuries and currently, Allen J. Tortorice and Laura L. Tortorice have been United States citizens, residing and domiciled in Dayton, Tennessee, and thus are citizens of the State of Tennessee.

B. The Defendant

10. Defendant Pfizer is incorporated in Delaware with its principal place of business in New York, New York, and is thus a citizen of the States of Delaware and New York. Pfizer researches, develops, produces, markets, and sells pharmaceuticals, including Xeljanz, throughout the United States, including Tennessee.

GENERAL ALLEGATIONS

A. Pfizer's Aggressive Marketing of Xeljanz

11. Xeljanz is a prescription medication that is part of a group of oral Janus kinase (JAK) inhibitors approved for the treatment of adult patients with moderate to severely active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), and moderate to severely active ulcerative colitis (UC).

12. Xeljanz is produced and sold by Pfizer. As a direct result of its unprecedented

direct-to-consumer and prescribing physician advertising campaigns[1], Pfizer has earned billions of dollars in sales from Xeljanz. In fact, Pfizer reported $1.77 billion in worldwide Xeljanz sales for 2017-2018 alone[2], making it one of the most profitable drugs in Pfizer's history. "There is an inherent tension between the desire for profit and scientific decisions that suggest warnings may well shrink the customer base because of the cautionary tone struck by the warnings."[3] That tension is evident here.

B. Pfizer Failed to Warn of Known Risks that Xeljanz Causes Severe Thromboembolic-Related Conditions

13. Xeljanz causes several dangerous adverse conditions, including an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death. These risks of Xeljanz became known to Pfizer, while Pfizer was engaged in its aggressive marketing efforts to establish Xeljanz as the standard of care in RA, PsA & UC treatment.

14. On September 1, 2021, based on a completed FDA review of a large, randomized safety clinical trial, the FDA concluded that they were requiring revisions to the Boxed Warning for Xeljanz/Xeljanz XR, to include information about the risks of serious heart-related events, cancer, blood clots, and death.

15. These increased risks are the type of risks that a reasonably prudent drug company should have prominently warned about in its prescription drug label and medication guide. Pfizer has the financial resources and internal processes in place to warn for the risks addressed in this lawsuit.

16. Pfizer failed to take such action because of the feared impact that warning doctors and the public would have on sales.

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[1] In January of 2019 alone, Pfizer spent over $40 million on direct-to-consumer national television advertising.
[2] Pfizer Press Release, 4th Quarter 2018-Profit and Earnings Report.
[3] *Hodges v. Pfizer, Inc.*, 14-cv-4855, 2015 WL 13804602, at *10 (D. Minn. Dec. 17, 2015).

17. Pfizer did not warn of the thromboembolic-related risks in the Xeljanz label. These risks were not included on the highlights page of the label -including as a "black box" warning[4].

18. Pfizer failed to warn doctors because of the feared impact that such warning would have on sales.

19. Pfizer's failure to warn doctors and patients of the serious risks of developing thromboembolic-related conditions associated with Xeljanz was grossly negligent, reckless, outrageous intentional, and part of an aggressive strategy to sell Xeljanz over competing drugs.

C. Laws and Regulations Governing the Approval and Labeling of Prescription Drugs

20. The Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act") requires manufacturers that develop a new drug product to file a New Drug Application ("NDA") in order to obtain approval from the Food and Drug Administration ("FDA") before selling the drug in interstate commerce. 21 U.S.C. § 355.

21. In December of 2011, the FDA accepted Pfizer's Xeljanz NDA for review for adult patients with moderate to severely active rheumatoid arthritis. On November 6, 2012, the FDA approved Pfizer's Xeljanz NDA for the rheumatoid arthritis indication.[5]

22. The NDA must include, among other things, data regarding the safety and effectiveness of the drug, information on any patents that purportedly cover the drug or a method of using the drug, and the labeling proposed to be used for the drug. 21 U.S.C. § 355(b).

23. Manufacturers with an approved NDA must review all adverse drug experience information obtained by or otherwise received by them from any source, including but not limited

[4] A "black box warning" appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks. *See*, https://www.fda.gov/media/74382/download.

[5] In February of 2016, the FDA approved Xeljanz XR for rheumatoid arthritis. In December of 2017, the FDA subsequently approved Xeljanz and Xeljanz XR for the treatment of active psoriatic arthritis, and in May 2018, the FDA approved Xeljanz for the treatment of moderate to severely active ulcerative colitis.

to post marketing experience, reports in the scientific literature, and unpublished scientific papers. 21 C.F.R. § 314.80(b).

24. After FDA approval, manufacturers may only promote drugs in a manner consistent with the contents of the drug's FDA-approved label. 21 C.F.R. § 202.1. The FDA's Division of Drug Marketing, Advertising, and Communications monitors manufacturers' promotional activities and enforces the FDCA and its implementing regulations to ensure compliance.

25. Although the FDA approves the label, the drug manufacturer has the duty to warn of dangerous side effects associated with its drug. Under what is known as the Changes Being Effected ("CBE") regulation, a manufacturer with an approved NDA can, among other things, add or strengthen a warning in its label without prior FDA approval by simply sending the FDA a "supplemental submission." 21 C.F.R. § 314.70(c)(6)(iii).

26. Specifically, the manufacturer can "add or strengthen a contraindication, warning, precaution, or adverse reactions for which the evidence of causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter" and "to add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." 21 C.F.R. § 314.70(c)(6)(iii)(A) and (C).

27. A manufacturer must revise its label "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitively established." 21 C.F.R. § 201.57(c)(6).

28. The warnings section of the label "must identify any laboratory tests helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information must be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed

before, during, and after therapy." *Id*. § 201.57(c)(6)(iii). According to an FDA Guidance for Industry on the warnings and precautions section of the labeling, "[i]nformation about the frequency of testing and expected ranges of normal and abnormal values should also be provided if available."[6]

29. Adverse reactions must be added to the label where there "is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." *Id*. § 201.57(c)(7).

30. An August 22, 2008 amendment to these regulations provides that a CBE supplement to amend the labeling for an approved product must reflect "newly acquired information." 73 Fed. Reg. 49609. "Newly acquired information" is not limited to new data but also includes "new analysis of previously submitted data." *Id*. at 49606. "[I]f a sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for 'newly acquired information.'" *Id*. at 49607.

D. Pfizer Could Have Unilaterally Strengthened the Xeljanz Drug Label After FDA Approval in the United States

31. Pfizer could have strengthened the Xeljanz label at any time under the CBE regulation without prior FDA approval. The CBE regulation permits manufacturers to strengthen drug labels based on "newly acquired information" – that is, information that was not previously presented to the FDA.

32. As described above, Pfizer received significant "newly acquired information" after

[6] FDA Guidance Document, Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format, October 2011, https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf (last visited, February 14, 2022).

the launch of Xeljanz that, through the CBE regulation, should have resulted in a label change warning of the risks of thromboembolic-related injury associated with Xeljanz.

33. While Pfizer had ample opportunity to strengthen its label to add a warning, Pfizer declined to do so.

34. Notably, it wasn't until September 1, 2021 that the Xeljanz label contained a warning regarding thromboembolic events. The label was updated to include warning regarding an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death, only after a label change was requested by the FDA. In response to FDA's request, Pfizer modified its label to include the following warning in the "warnings and precautions" section:

> Thrombosis, including pulmonary, deep venous and arterial, some fatal: Reported more commonly in patients treated with XELJANZ 10 mg twice daily compared to 5 mg twice daily. Avoid XELJANZ/XELJANZ XR/XELJANZ Oral Solution in patients at risk. Promptly evaluate patients with symptoms of thrombosis and discontinue XELJANZ/XELJANZ XR/XELJANZ Oral Solution. (5.4).

35. Instead of seizing the opportunity to adequately warn doctors regarding severe and life-threatening conditions, Pfizer instead made affirmative efforts to ensure the warning was as innocuous as possible.

E. Plaintiff Suffered Thromboembolic-related injury

36. Allen J. Tortorice was diagnosed with Rheumatoid Arthritis in 2008.

37. Allen J. Tortorice took Xeljanz from approximately January 2017 to February 2021.

38. In February 2021, Allen J. Tortorice started experiencing symptoms such as bloating, loss of appetite and overall malaise, which at the time he thought had something to do with his gallbladder. Consequently, on February 23, 2021, Allen J. Tortorice visited his primary

care physician, Dr. Christopher Hurton, who examined him and referred him to Rhea County Medical Center's emergency room. A scan was performed In Rhea County Medical Center, where they discovered the thromboembolic event. Immediately, he was transferred to Parkridge Medical Center, where the cardiologist determined he needed emergency heart surgery. Allen J. Tortoise was then transferred by ambulance to TriStar Centennial Medical Center.

39. As a result of his use of Xeljanz, Allen J. Tortorice suffered from a blood clot which resulted in subsequent hospitalization, aortic valve replacement and bypass surgery in TriStar Centennial Medical Center on February 26, 2021, all directly caused by his ingestion of Xeljanz. He was released from the hospital on March 12, 2021.

40. As described above, at no time before or during the time that Allen J. Tortorice took Xeljanz did the Xeljanz label adequately warn of the risks of cardiovascular and thromboembolic-related conditions associated with the drug regarding patients diagnosed with RA.

41. At no time during his use of Xeljanz did Allen J. Tortorice know or have reason to know that serious heart-related events such as heart attack or stroke, cancer, blood clots, and death were related to Xeljanz use.

42. Plaintiff Allen J. Tortorice recently discovered that his injuries are related to his Xeljanz use and is still engaged in extensive rehabilitation as a direct result of Pfizer's negligent, misleading, fraudulent and other wrongful acts and omissions in connection with the sale, labeling, pharmacovigilance and false and misleading promotion of its drug, Xeljanz.

F. Exemplary/Punitive Damages Allegations

43. Pfizer's conduct, as alleged herein, was done with reckless disregard for human life, oppression, and malice. Pfizer was fully aware of the safety risks of Xeljanz. Nonetheless, Pfizer deliberately crafted their label, marketing, and promotion to mislead consumers.

44. This was not done by accident. Rather, Pfizer knew that it could turn a profit by convincing physicians and consumers that Xeljanz came without certain, harmful risks. Pfizer further knew that full disclosure of the true risks of Xeljanz would limit the amount of money it would make selling the drug. Pfizer's object was accomplished not only through inadequate warnings in their label, but through a comprehensive scheme of misleading marketing.

45. Plaintiff's serious injuries were a foreseeable and proximate result of Pfizer's false and misleading information it disseminated to physicians and patients, which contained inaccurate, deceptive, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of Xeljanz. Plaintiff's physician and Plaintiff were denied the right to make an informed decision about whether to prescribe and take Xeljanz, knowing the full risks associated to its use. Such conduct was done with conscious disregard of Plaintiff's rights.

46. Accordingly, Plaintiffs request punitive damages against Pfizer for the harms caused to Plaintiffs.

CLAIMS FOR RELIEF

COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

47. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

48. Defendant designed, tested, manufactured, marketed, distributed, and supplied Xeljanz. As such, Defendant had a duty to adequately test the product in conformance with the standards of care to ensure that the risks and benefits of the drug were sufficient for the safe and effective use of the drug for its approved indications, and to warn healthcare providers, including hospitals, clinics, prescribers, and patients, including Plaintiff, of the health risks and dangers associated with using the medication, both in the premarketing and post-approval lifecycle phases

of Xeljanz.

49. At all relevant times, Pfizer engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Xeljanz, which is defective and unreasonably dangerous to consumers, including Plaintiff, because it did not contain adequate warnings or instructions concerning its dangerous characteristics. These actions were under the ultimate control and supervision of Pfizer. At all relevant times, Pfizer registered, researched, manufactured, distributed, marketed, and sold Xeljanz within this judicial district. Pfizer was, at all relevant times, involved in the sale and promotion of Xeljanz products marketed and sold in this judicial district.

50. Pfizer researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released Xeljanz into the stream of commerce and, in the course of same, directly advertised or marketed Xeljanz to consumers and end-users, including Plaintiff. Pfizer, therefore, had a duty to adequately warn of the thromboembolic-related risks associated with the use of Xeljanz.

51. At all relevant times, Pfizer had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure Xeljanz did not cause users, like Plaintiff, to suffer from unreasonable and dangerous risks. Pfizer had a continuing duty to warn users, including Plaintiff, of dangers associated with Xeljanz. Pfizer, as a manufacturer, seller, or distributor of pharmaceutical medications, is held to the knowledge of an expert in the field.

52. At the time of manufacture, Pfizer could have provided warnings or instructions regarding the full and complete risks of Xeljanz, because Pfizer knew, or should have known, of the unreasonable risks of harm associated with the use of and/or exposure to Xeljanz.

53. At all relevant times, Pfizer failed and deliberately refused to investigate, study, test, or promote the safety or minimize the dangers to those who would foreseeably use or be harmed by Xeljanz, including Plaintiff.

54. Even though Pfizer knew, or should have known, that Xeljanz posed a severe risk of harm, it failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure. The dangers of Xeljanz, as described above, were known to Pfizer, or scientifically knowable to Pfizer, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product, and were not known to end-users and consumers, such as Plaintiff.

55. Pfizer knew or should have known that Xeljanz created significant risks of serious bodily harm to consumers, as alleged herein, and Pfizer failed to adequately warn consumers, *i.e.*, the reasonably foreseeable users, of the risks of exposure to the drug. Pfizer has wrongfully concealed information concerning the dangerous nature of Xeljanz and has made false and/or misleading statements concerning its safety.

56. At all relevant times, Xeljanz reached intended consumers, handlers, and users or other persons coming into contact with the product within this judicial district and throughout the United States, including Plaintiff, without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and marketed by Pfizer.

57. Plaintiff was exposed to Xeljanz without knowledge of its dangerous characteristics.

58. At all relevant times, Plaintiff used and/or was exposed to Xeljanz while using the drug for its intended or reasonably foreseeable purpose, without knowledge of its dangerous characteristics.

59. Plaintiff could not have reasonably discovered the defects and risks associated with Xeljanz prior to or at the time of consuming Xeljanz. Plaintiff relied upon the skill, superior knowledge, and judgment of Pfizer to know about and disclose serious health risks associated with using Xeljanz.

60. Pfizer knew or should have known that the minimal warnings disseminated with Xeljanz were inadequate, failed to communicate adequate information on the dangers of sustaining severe thromboembolic-related injuries, and failed to communicate warnings and instructions that were appropriate and adequate to render Xeljanz safe for its ordinary, intended, and reasonably foreseeable use.

61. The information that Pfizer did provide or communicate failed to contain relevant, adequate warnings, hazards, and precautions that would have enabled consumers, such as Plaintiff, to consume Xeljanz safely. Instead, Pfizer disseminated information that was inaccurate, incomplete, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of Xeljanz. In fact, Pfizer continued to aggressively promote the efficacy and safety of Xeljanz, even after they knew or should have known of the unreasonable risks from use. Pfizer also concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of Xeljanz.

62. This failure to warn is not limited to the information contained on Xeljanz's labeling. Pfizer was able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Xeljanz through other, non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. Instead, Pfizer did not disclose the known, severe risks of Xeljanz through any medium.

63. Pfizer is liable to Plaintiffs for injuries caused by its negligent or willful failure, as described above, to provide adequate warnings or other clinically relevant information and data regarding the risks associated with Xeljanz.

64. Had Pfizer provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with Xeljanz, Plaintiff could have avoided the risk of developing thromboembolic-related injuries and could have obtained or used alternative medication.

65. As a direct and proximate result of Pfizer placing defective Xeljanz drugs into the stream of commerce, Plaintiff was injured and has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

66. As a proximate result of Pfizer placing defective Xeljanz drugs into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiffs suffered great mental anguish and other personal injury and damages.

67. As a proximate result of Pfizer placing defective Xeljanz drugs into the stream of commerce, as alleged herein, Plaintiffs sustained loss of income and/or loss of earning capacity.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT II: FRAUD AND FRAUDULENT INDUCEMENT

68. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full herein.

69. Defendant is under a duty to ensure that the prescription Xeljanz label is accurate and contains the essential scientific information for the safe and effective use of the drug. 21 C.F.R. §201.56. Defendant may not disseminate prescription labeling that constitutes a misrepresentation

of the material facts regarding the risk and benefits of Xeljanz, particularly when it knows that new safety information renders the existing inaccurate. 21 C.F.R. §1.21.

70. Under the Code of Federal Regulations, Defendant has a duty to ensure its Xeljanz warnings to the medical community are accurate, adequate, and not false or misleading in any particular. Defendant also has a duty to conduct sufficient post market safety surveillance; to review all adverse drug event information; to report any safety information bearing on the risk-benefit profile associated with Xeljanz to the medical community; and to update its labeling and otherwise inform and educate Plaintiff's prescribing physician, Plaintiff, and other foreseeable users about new safety information.

71. Defendant breached its duty to the medical community, Plaintiff's prescribing physician, Plaintiff, and other foreseeable users of Xeljanz because it failed to provide adequate accurate and adequate Xeljanz warnings, precautions, information for patients, and adequate instructions for use as outlined above.

72. Defendant breached its duty to the medical community, Plaintiff's prescribing physician, Plaintiff and other similarly situated foreseeable users because it failed to conduct adequate premarketing and post market safety assessments/surveillance of Xeljanz and failed to report all of the significant safety and efficacy data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Xeljanz.

73. Defendant breached its duty to the medical community, Plaintiffs; prescribing physician, Plaintiffs and other similarly situated foreseeable users because it failed to adequately assess and review all adverse events -both before approval and after approval of Xeljanz- and to report, disclose and inform prescribers about this safety information bearing upon the adequacy and/or accuracy of its warnings, including the risks and/or prevalence of side effects caused by

Xeljanz, an increase in adverse event reports accurately code adverse event cases.

74. Defendant breached its duty to the medical community, Plaintiff's prescribing physician, Plaintiffs and other similarly situated foreseeable users because it failed to periodically review all medical literature and failed to report significant data concerning the efficacy and safety of Xeljanz, including but not limited to an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death.

75. Defendant knew, or should have known through the exercise of reasonable care, that the package insert and label for Xeljanz substantially failed to state at all, or grossly understated, the relative risks and/or degree of risks of severe side effects associated with Xeljanz that are described herein.

76. At all material times, Defendant was engaged in the business of manufacturing, marketing, distributing, promoting, and selling. Defendant made misrepresentations of material facts to, omitted and/or concealed material facts from Plaintiff's prescribing physician and Plaintiff during the life cycle of the product (including but not limited to each time a prescription was written or filled, when the safety information identified above emerged, each time Pfizer updated its label and failed to include the warnings at issue, and in the promotion, advertising, marketing, distribution and sale of Xeljanz regarding its efficacy, safety, and directions for use.

77. Defendant deliberately and intentionally misrepresented to, and omitted and/or concealed material facts from, consumers, including Plaintiffs, and Plaintiff's prescribing physician, that Defendant's product Xeljanz was safe when used as intended.

78. Defendant concealed facts known to it, as alleged herein, in order to ensure increased sales of Defendant's product Xeljanz, without providing all of the essential scientific information for the safe and effective use of the product, through applications to FDA, press

releases, patient information leaflets, and/or medication guides, promotional materials or through other risk communication mediums that are used by drug makers to inform medical community and patients, and other entities regarding the true risk-benefit profile of Xeljanz.

79. Defendant had a duty to disclose the foregoing risks and failed to do so, despite possession of information concerning those risks. Defendant's representations that Defendant's product Xeljanz was safe for its intended purpose were false, misleading, as Defendant's product Xeljanz was in fact dangerous.

80. Further, Defendant failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Xeljanz. Defendant also failed to exercise reasonable care in communicating the information concerning Xeljanz to Plaintiff and Plaintiff's prescribing physician, and/or concealed facts that were known to Defendant.

81. Plaintiffs were not aware of the falsity of the foregoing representations, nor were Plaintiffs aware that material facts concerning the safety of Defendant's product Xeljanz had been concealed or omitted. In reliance upon Defendant's misrepresentations, and the absence of disclosure of the serious health risks, Plaintiff ingested Xeljanz. Had Plaintiff or Plaintiff's prescribing physician known the true facts concerning the risks associated with Xeljanz, Plaintiff would not have taken it.

82. The reliance by Plaintiff and Plaintiff's prescribing physician upon Defendant's misrepresentations was justified because misrepresentations and omissions were made by individuals and entities that were in a position to know the true facts concerning Defendant's product Xeljanz. Plaintiff and Plaintiff's prescribing physician were not in a position to know the true facts because Defendant aggressively promoted the use of Defendant's product Xeljanz and concealed the risks associated with its use, thereby inducing Plaintiff and his prescribing physician

to use and prescribe Defendant's product Xeljanz.

83. As a direct and proximate result of Defendant's misrepresentations, and/or concealment, Plaintiffs suffered injury and harm as previously alleged herein.

84. Defendant's conduct in concealing material facts and making the foregoing misrepresentations, as alleged herein, was committed with conscious or reckless disregard of the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiffs to punitive damages in an amount to be determined at trial that is appropriate to punish Defendant and deter it from similar conduct in the future. Plaintiffs are not alleging any cause of action for fraud on the FDA.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT III - BREACH OF IMPLIED WARRANTY

85. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full herein.

86. Defendant manufactured, marketed, sold, and distributed Xeljanz.

87. At the time Defendant marketed, sold, and distributed Xeljanz for use by Plaintiff, Defendant knew of the purpose for which Xeljanz was intended and impliedly warranted Defendant's product Xeljanz to be of merchantable quality and safe and fit for such use.

88. Plaintiff and Plaintiff's prescribing physician reasonably relied on the skill, superior knowledge, and judgment of Defendant as to whether Xeljanz was of merchantable quality and safe and fit for its intended use.

89. Due to Defendant's wrongful conduct as alleged herein, Plaintiffs and Plaintiff's prescribing physician could not have reasonably known about the risks and side effects associated

with Xeljanz until after Plaintiff ingested it and was injured because there were no warnings and/ or adequate warnings and directions for use for Xeljanz as alleged herein.

90. Contrary to such implied warranty, Defendant's product Xeljanz was not of merchantable quality and was not safe or fit for its intended use. Moreover, Defendant knew that its statements were false and that Xeljanz lacked the most basic degree of fitness for ordinary use, including the ability to be consumed and Defendant knew that its omissions rendered Defendant's statements false or misleading.

91. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiffs suffered conscious pain and suffering and suffered injury and harm as previously alleged herein.

92. Defendant's conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount to be determined at trial that is appropriate to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IV - BREACH OF EXPRESS WARRANTY

93. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full herein.

94. Defendant manufactured, marketed, sold, and distributed Xeljanz.

95. At the time Defendant marketed, sold, and distributed Xeljanz for use by Plaintiff, Defendant knew of the purpose for which Xeljanz was intended and expressly warranted

Defendant's product Xeljanz to be of merchantable quality and safe and fit for such use.

96. Plaintiffs and Plaintiff's prescribing physician reasonably relied on the skill, superior knowledge, and judgment of Defendant as to whether Xeljanz was of merchantable quality and safe and fit for its intended use.

97. Due to Defendant's wrongful conduct as alleged herein, Plaintiffs and Plaintiff's prescribing physician could not have reasonably known about the risks and side effects associated with Xeljanz until after Plaintiff ingested it and was injured because there were no warnings and/ or adequate warnings and directions for use for Xeljanz as alleged herein.

98. Contrary to such express warranty, Defendant's product Xeljanz was not of merchantable quality and was not safe or fit for its intended use. Moreover, Defendant knew that its statements were false and that Xeljanz lacked the most basic degree of fitness for ordinary use, including the ability to be consumed and Defendant knew that its omissions rendered Defendant's statements false or misleading.

99. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs suffered conscious pain and suffering and suffered injury and harm as previously alleged herein.

100. Defendant's conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount to be determined at trial that is appropriate to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT V: NEGLIGENCE

101. Plaintiffs incorporate by reference each and every paragraph of the Complaint as though set forth in full herein.

102. Defendant owed a duty to Plaintiff's prescribing physicians and Plaintiffs to use reasonable care in testing, labeling, manufacturing, marketing, supplying, distributing and selling Xeljanz, including a duty to ensure that Xeljanz did not cause users to suffer from unreasonable, unknown, and dangerous side effects.

103. Defendant failed to exercise reasonable care and failed to warn of the known risks associated with the risks of Xeljanz. The product lacked sufficient warnings regarding the hazards and dangers to users of Xeljanz, and failed to provide safeguards to prevent the injuries sustained by Plaintiff. Defendant failed to properly test, analyze and report on the safety profile of Xeljanz prior to its sale, and as a result, subjected users to an unreasonable risk of injury when those products were used as directed.

104. In addition to those reasons set forth above, Defendant breached its duty and was negligent in its actions, misrepresentations, and omissions towards Plaintiffs in the following ways:

a. Failed to exercise due care in developing, testing, marketing labeling and manufacturing Xeljanz to avoid the aforementioned risks to individuals involving those products during the Xeljanz lifecycle;

b. Failed to include adequate directions for use and warnings with Xeljanz to alert prescribers and Plaintiffs of its potential risks and side effects;

c. Failed to adequately and properly test Xeljanz before placing it on the market by not disclosing all risks in its studies, applications, labeling, and marketing and advertising materials and documents;

d. Failed to conduct sufficient clinical testing on Xeljanz, which if properly performed would have shown that Xeljanz had serious side effects, including but not limited to an increased risk of serious heart-related events such as heart attack or stroke,

cancer, blood clots, and death.

e. Failed to adequately warn Plaintiffs and Plaintiff's prescribing physicians regarding the an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death, failed to conduct adequate pharmacovigilance and prepare a pharmacovigilance assessment and plan to mitigate the risks; and failed to warn through various communication vehicles, including patient information leaflets or patient medication guides, press releases, and other risk communication vehicles;

f. Failed to provide adequate post-marketing warning or instructions after Defendant knew or should have known of the significant risk identified herein;

g. Placed an unsafe product into the stream of commerce; and

h. Was otherwise careless or negligent.

105. Defendant knew or should have known that Xeljanz caused unreasonably dangerous risks and serious side effects of which Plaintiffs and Plaintiff's prescribing physician would not be aware. Defendant nevertheless advertised, marketed, sold, and/or distributed Xeljanz, despite knowing of its unreasonable risks of injury.

106. Defendant knew or should have known that consumers such as Plaintiff would suffer injury as a result of Defendant's failure to exercise reasonable care as described above.

107. Upon information and belief, Defendant knew or should have known of the defective nature of Xeljanz, as set forth herein, but continued to manufacture, market, and sell Xeljanz so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs and Plaintiff's prescribing physician, in conscious and/or negligent disregard of the foreseeable harm caused by the medication.

108. Defendant failed to disclose to Plaintiffs and Plaintiffs' prescribing physician facts known or available to Defendant in order to ensure continued and increased sales of Xeljanz. This failure to disclose deprived Plaintiff of the information necessary for Plaintiff and Plaintiff's prescribing physician to weigh the true risks of taking Xeljanz against the benefits.

109. As a direct and proximate result of Defendant's negligence, Plaintiffs suffered harm as alleged herein, including severe pain and suffering, loss of enjoyment of life, economic loss, out-of-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Plaintiff's ingestion of harmful and defective product. As a result, the imposition of punitive damages against Defendant is warranted.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

CAUSE VI - NEGLIGENT MISREPRESENTATION

110. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full herein.

111. Defendant owed a duty to disseminate accurate and adequate information concerning Xeljanz, and to exercise reasonable care to ensure that it did not, in those undertakings, create unreasonable risks of personal injury to others.

112. Defendant disseminated to physicians, including Plaintiff's prescribing physician, through package insert and other mediums, information concerning the properties, safety profile and effects of Xeljanz, with the intention that physicians would rely upon that information when making a decision concerning whether to prescribe Xeljanz for their patients.

113. Defendant has a duty to ensure that the information contained in the package inserts, patient information leaflets, and medication guides accompanying its prescription drug products is accurate, complete, and is not misleading, or inadequate. Defendant had a duty to monitor medical literature and post marketing adverse events and to report any data affecting the safety of the drug to the FDA, Plaintiff's physicians, and through them directly to the Plaintiff.

114. Defendant knew that Plaintiff's prescribing physician would rely upon Xeljanz labeling and information disseminated to Defendant, and that many patients would be likely to ingest Xeljanz as a result of Defendant's labeling safety communications and advertising efforts.

115. The representations by Defendant were false and misleading and were intended to induce reliance on those misrepresentations and the purchase and use of Xeljanz and, as a result, Defendant knew or should have known that those misrepresentations would have resulting in the ingestion of Xeljanz by consumers such as Plaintiff. Had Plaintiff or his prescribing physician known of the true facts and those facts concealed by Defendant, Plaintiff's prescribing physician would not have prescribed Xeljanz to Plaintiff and Plaintiff would not have ingested Xeljanz and been injured. The reliance by Plaintiff's prescribing physician and Plaintiff on Defendant's misrepresentations was justified because such misrepresentations were made and conducted by Defendant, who was in a position to know and did know the true facts.

116. As a proximate and foreseeable result of the negligent misrepresentations of Defendant, Plaintiff suffered severe bodily injury and consequent economic and other loss as previously described.

117. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiffs suffered harm as alleged herein, including severe pain and suffering, loss of enjoyment of life, economic loss, out-of-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Plaintiff's ingestion of harmful and defective product. As a result, the imposition of punitive damages against Defendant is warranted.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VII - GROSS NEGLIGENCE

118. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full herein.

119. Defendant had the duty to exercise reasonable care in testing, manufacturing, marketing, labeling, selling, and/or distributing Xeljanz including a duty to ensure that Xeljanz did not cause users to suffer from unreasonable and dangerous side effects.

120. Defendant failed to exercise reasonable care in testing, manufacturing, marketing, labeling, selling, and/or distributing Xeljanz for the reasons set forth above.

121. As a direct and proximate result of the Defendant's sale of Xeljanz without adequate warnings, Plaintiffs suffered harm as alleged herein. All of Plaintiff's injuries have caused and continue to cause Plaintiffs intense anxiety, distress, fear, loss of enjoyment of life, pain and suffering and distress.

122. As a direct result of Defendant's gross negligence, willful and wanton misconduct, and/or other wrongdoing and actions, which constitute a deliberate act or omission with knowledge of a high degree of probability of harm and reckless indifference to the consequences, Plaintiff will in the future be required to obtain medical and/or hospital care, attention and services. As a result, Plaintiffs may incur expenses for such health care treatment in an amount not yet ascertained.

123. Defendant continued to promote the efficacy and safety of Xeljanz, while providing little or no warnings, and downplayed the risks, even after Defendant knew of the risks and injuries associated with its use. Defendant's conduct was committed with knowing, conscious and/or deliberate disregard for the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish Defendant and deter Defendant

from similar conduct in the future.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VIII – LOSS OF CONSORTIUM

124. Plaintiffs incorporate by reference every allegation set for in the preceding paragraphs as if fully stated herein.

125. At all relevant times herein, Plaintiff Laura Tororice was and is married to Plaintiff Allan Tortorice.

126. By reason of the forgoing, Plaintiff Laura Tortorice has been caused and in the future the loss of her husband, Plaintiff Allan Tortorice's companionship, services and society.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Pfizer, awarding Plaintiffs any and all damages available to Plaintiffs under the law, including but not limited to:

1. General damages according to proof;
2. Medical and incidental expenses according to proof;
3. All losses because Plaintiff will not be able to pursue Plaintiff's usual occupation and activities according to proof;
4. For loss of consortium, companionship, comfort, affection, fellowship, society, solace, moral support, and assistance according to proof;
5. For pain and suffering and emotional distress according to proof;

6. Punitive and exemplary damages sufficient to punish and make an example of each Pfizer according to proof;

7. Plaintiffs' reasonable attorneys' fees and costs;

8. Prejudgment interest; and

9. For any other relief this Court deems appropriate.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial for all issues so triable in this action.

Dated: February 17, 2022

Respectfully Submitted,

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